Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant.

2. (Currently amended) ~~A~~ The method according to claim 2, wherein the antigen or immunogenic derivative thereof is derived from an organism selected from the ~~following~~ group of: Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from Neisseria spp, Moraxella spp, Bordetella spp; Mycobacterium spp., including M. tuberculosis; Escherichia spp, including enterotoxic E. coli; Salmonella spp,; Listeria spp; Helicobacter spp; Staphylococcus spp., including S. aureus, S. epidermidis;; Borrelia spp; Chlamydia spp., including C. trachomatis, C. pneumoniae; Plasmodium spp., including P. falciparum; Toxoplasma spp., and Candida spp.

3. (Currently amended) A method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour-associated antigen or immunogenic derivative thereof and a CpG adjuvant.

4. (Currently amended) ~~A~~ The method according to claim 3, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group ~~comprising~~ of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, ~~or~~ and her 2 neu.

5. (Currently amended) ~~A~~ The method according to ~~any of~~ claims 1 ~~to 4~~, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously, separately or sequentially in any order.

6. (Currently amended) ~~A~~ The method according to claim 5, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously in the form of a combined pharmaceutical preparation.

7. (Currently amended) ~~A~~ The method according to ~~any of~~ claims 1 ~~to 6~~, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

8. (Currently amended) ~~A~~ The method according to claim 7, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

9. (Currently amended) ~~A~~ The method according to ~~any of~~ claims 1 ~~to 7~~, wherein the CpG adjuvant comprises a Purine, Purine, C, G, pyrimidine, pyrimidine sequence.

10. (Currently amended) ~~A~~ The method according to ~~any of~~ claims 1 ~~to 8~~, wherein said CpG adjuvant is selected from the group ~~comprising~~ of: TCC ATG ACG TTC CTG ACG TT (SEQ ID NO:1); TCT CCC AGC GTG CGC CAT (SEQ ID NO:2); ACC GAT GAC GTC GCC GGT GAC GGC ACC ACG (SEQ ID NO:3); TCG TCG TTT TGT CGT TTT GTC GTT (SEQ ID NO:4); and TCC ATG ACG TTC CTG ATG CT (SEQ ID NO:5).

11. (Currently amended) ~~A~~ The method according to ~~any of~~ claims 1 ~~to 8~~, wherein said CpG adjuvant contains at least two unmethylated CG repeats ~~being~~ that are separated at least by 3 nucleotides.

12. (Currently amended) ~~A~~ The method according to claim 11, wherein the immunostimulatory oligonucleotide contains at least two unmethylated CG repeats ~~being~~ that are separated by 6 nucleotides.

13. (Original) A combined preparation comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

14. (Currently amended) ~~A~~ The combined preparation according to claim 13, wherein components (1) and (2) are admixed in a composition.

15. (Currently amended) ~~A~~ The combined preparation according to claim 13, ~~or 14~~ wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

16. (Currently amended) ~~A~~ The combined preparation according to claim 15, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group ~~comprising~~ of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, ~~or~~ and her 2 neu.

17. (Currently amended) ~~A~~ The combined preparation according to ~~any of~~ claim~~s~~ 13 ~~to 16~~, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

18. (Currently amended) ~~A~~ The combined preparation according to claim 17, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or an bioactive fragment or derivative thereof.

19. (Currently amended) ~~A~~ The combined preparation according to ~~any of~~ claim~~s~~ 13 ~~to 18~~, wherein the CpG adjuvant ~~is as defined in any of claims 9 to 12~~ comprises a Purine, Purine, C, G, pyrimidine, pyrimidine sequence.

20. (Currently amended) ~~Combined~~ The combined preparation as claimed in ~~any of~~ claims 13 ~~to 19 in which~~ , wherein the immunogenic composition additionally comprises an immunostimulant chemical selected from the group ~~comprising~~ of: 3D-MPL, QS21, a mixture of QS21 and cholesterol, aluminium hydroxide, aluminium phosphate, tocopherol, and an oil in water emulsion ~~or a combination of two or more of the said adjuvants~~.

21. (Currently amended) ~~Combined~~ The combined preparation as claimed in claim 20, wherein the immunogenic composition adjuvant comprises 3D-MPL, CpG, QS21, cholesterol, an oil in water emulsion.

22. (Currently amended) ~~Combined~~ The combined preparation as claimed in claim 21, wherein the oil in water emulsion comprises squalene, tocopherol and polyoxyethylenesorbitan monooleate (Tween 80).

23. (Currently amended) ~~Combined~~ The combined preparation as claimed in claim 20, wherein the immunogenic composition comprises QS21, cholesterol and a CpG adjuvant.

24. (Currently amended) ~~Combined~~ The combined preparation as claimed in ~~any of~~ claims 13 ~~to 23~~, wherein both active components are in the form of injectable solutions.

25. (Original) A pharmaceutical kit comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment thereof and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, and auto-immune diseases.

26. (Currently amended) ~~A~~ The pharmaceutical kit according to claim 25, wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

27. (Currently amended) ~~A~~ The pharmaceutical kit according to claim 26, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group ~~comprising~~ of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, ~~or~~ and her 2 neu.

28. (Currently amended) ~~A~~ The combined preparation as claimed in ~~any of~~ claim~~s~~ 13 ~~to 23~~ for use in ~~medicine~~ medicine.

29. (Currently amended) ~~A~~ The method as claimed in ~~any of~~ claim~~s~~ 1 ~~to 12~~ ~~which~~ that comprises the use of a combined preparation ~~according to any of claims 13 to 24~~ comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

30.-35. (Cancelled)

36. (New) A method of treating a patient suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions comprising administering an IL-18 polypeptide or bioactive fragment or derivative thereof to the patient, wherein the patient has already been primed with an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant.

37. (New) A method of treating a patient suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions comprising administering an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant to the patient, wherein the patient has already been primed with an IL-18 polypeptide or bioactive fragment or derivative thereof.

38. (New) The method as claimed in claim 36, wherein the antigen is a tumour-associated antigen, and the cancer is selected from the group of: breast

cancer, lung cancer, NSCLC, colon cancer, melanoma, ovarian cancer, bladder cancer, head and neck squanmous carcinoma, and esophageal cancer.

39. (New) The method according to claim 36, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

40. (New) The method according to claim 39, wherein IL-18 is the polypeptide of SEQ ID NO:6 or SEQ ID NO:7 or bioactive fragment or derivative thereof.

41. (New) The method according to claim 26, wherein the CpG adjuvant comprises a Purine, Purine, C, G, pyrimidine, pyrimidine sequence.

42. (New) The combined preparation as claimed in claim 13, wherein the immunogenic composition additionally comprises at least two immunostimulant chemicals selected from the group of: 3D-MPL, QS21, a mixture of QS21 and cholesterol, aluminium hydroxide, aluminium phosphate, tocopherol, and an oil in water emulsion.